

AMENDED IN ASSEMBLY MAY 2, 2006

AMENDED IN ASSEMBLY APRIL 17, 2006

AMENDED IN ASSEMBLY MARCH 27, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2757

Introduced by Assembly Member Evans

February 24, 2006

An act to add Sections 1241.1 and 1265.1 to the Business and Professions Code, and to add Section 14115.41 to the Welfare and Institutions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 2757, as amended, Evans. Primary care clinics.

Existing law provides for the licensure and regulation of clinical laboratories and of primary care clinics by the State Department of Health Services. Under existing law, the department is required to approve a licensure application submitted by a primary care clinic meeting specified criteria for its affiliate clinic if, among other matters, both have the same corporate officers and are owned and operated by the same nonprofit organization with the same board of directors.

~~This bill would authorize a primary care clinic to apply to the department for licensure of the affiliate's clinical laboratory at the same time as it applies for the affiliate's licensure as a primary care clinic. The bill would also authorize a primary care clinic to use the clinical laboratory of any other primary care clinic that is owned and operated by the same nonprofit organization with the same board of directors. This bill would further provide that an application submitted~~

~~pursuant to these provisions shall be subject to all applicable laboratory licensing laws and regulations.~~

This bill would authorize a primary care clinic that has submitted an application for license with the department to also apply for licensure or registration of a clinical laboratory that would be operated by the primary care clinic. This bill would permit a primary care clinic that is operating within a network of primary care clinics, as defined, to establish a central laboratory, as specified, if used for the network's patients.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care benefits.

Existing law generally regulates the reimbursement of providers for Medi-Cal program services.

This bill would provide that any provision of law restricting reimbursement for clinical laboratory services to the provider who actually performs those services shall not prohibit reimbursement from being made to a primary care clinic when clinical laboratory services are performed at a ~~different location~~ *central laboratory* if the clinic and the laboratory are owned and operated by the same nonprofit corporation ~~and~~, the laboratory services are performed on a specimen collected at the clinic for a clinic patient, *and the clinic provides, where appropriate, specified information on the claim form when it bills for specified purposes.*

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1241.1 is added to the Business and
2 Professions Code, to read:
3 1241.1. (a) A primary care clinic, ~~as defined in Section 1200~~
4 ~~of the Health and Safety Code, may use the clinical laboratory of~~
5 ~~any other primary care clinic to perform a clinical laboratory test~~
6 ~~or examination if both clinics are owned by the same nonprofit~~
7 ~~organization having the same board of directors and the clinical~~
8 ~~laboratory is authorized under Section 1265 to perform the test or~~
9 ~~examination; licensed pursuant to subdivision (a) of Section 1204~~
10 *of the Health and Safety Code, that is operating within a network*

1 *of primary care clinics, may establish a central laboratory if all*
2 *of the following conditions are met:*

3 *(1) The central laboratory's sole purpose is performing*
4 *moderate or high complexity clinical laboratory tests and*
5 *examinations, or both, for the patients of the clinics in the*
6 *network.*

7 *(2) Prior to performing any tests or examinations, the central*
8 *laboratory obtains a certificate under the federal Clinical*
9 *Laboratory Improvement Act (CLIA) and a state laboratory*
10 *license for the appropriate complexity level of clinical laboratory*
11 *testing pursuant to Section 1265.*

12 *(b) For purposes of this section, "network of primary care*
13 *clinics" means two or more primary care clinics operated by the*
14 *same nonprofit corporation with the same board of directors and*
15 *the same corporate officers, and operating under the same*
16 *procedures and protocols.*

17 SEC. 2. Section 1265.1 is added to the Business and
18 Professions Code, to read:

19 1265.1. (a) A primary care clinic ~~submitting an application~~
20 ~~for licensure of an affiliate pursuant to Section 1218.1 of the that~~
21 *has submitted an application to the State Department of Health*
22 *Services for clinic licensure pursuant to subdivision (a) of*
23 *Section 1204 of the Health and Safety Code, may submit at the*
24 ~~same time~~ *an application for licensure or registration of a*
25 *clinical laboratory to be located on the premises of, and operated*
26 ~~by, the affiliate. operated by the clinic.~~

27 (b) An application for licensure of a clinical laboratory
28 submitted pursuant to this section shall be subject to all
29 applicable laboratory licensing laws and regulations, including,
30 but not limited to, any statutory or regulatory timelines and
31 processes for review of a clinical laboratory application.

32 SEC. 3. Section 14115.41 is added to the Welfare and
33 Institutions Code, to read:

34 14115.41. Notwithstanding any other provision of law
35 restricting reimbursement for clinical laboratory services to the
36 provider who actually performs those services, the restriction
37 shall not prohibit reimbursement from being made to a primary
38 care clinic when clinical laboratory services are performed at a
39 ~~different location~~ *central laboratory as authorized pursuant to*

1 Section 1241.1 of the Business and Professions Code, if ~~both~~ all
2 of the following conditions are met:

3 (a) The clinic and the *licensed central* laboratory performing
4 the services are owned and operated by the same nonprofit
5 corporation *with the same board of directors and the same*
6 *corporate officers*.

7 (b) The laboratory services are performed on a specimen
8 collected at the clinic for a clinic patient.

9 (c) *When the clinic bills for the moderate or high complexity*
10 *laboratory services performed by the central laboratory, the*
11 *clinic identifies on the claim form the license number and*
12 *address of the central laboratory, and provides any additional*
13 *information required by the department.*